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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,233	02/19/2002	Huaming Wang	GC567-C1	4433

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER

MOORE, WILLIAM W

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,233

Applicant(s)

WANG, HUAMING

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,8,11-20,23-37,39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 8,11-20,23-37,44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,36,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's Response of March 23, 2004, to a Notice of Non-Compliant Amendment mailed March 12, 2004, has been entered. This communication restarts the period for response set in another office communication mailed March 17, 2004; only five days after the Notice of Non-Compliant Amendment was mailed. The complete text of the withdrawn claims 11-20, 44 and 45 appears in Applicant's Response of March 23, 2004, but the status of claims 8 and 23-37 is still omitted. It is however recognized that, like claims 11-20, 44 and 45, the omitted claims 8 and 23-37 were also withdrawn from consideration by the examiner in the communication mailed July 15, 2003, as drawn to a non-elected invention. The amendment in the Response of March 23, 2004, cancels claims 40 and 41 and amends claims 2 and 39. Prior art rejections stated in the Office Action mailed July 15, 2003, are withdrawn in view of Applicant's amendment to page 1 of the specification perfecting a claim of priority to the December 22, 1998, filing date of the parent application serial No. 09/219702, of which this application is a continuation. This communication hereinafter recapitulates the text of objections and rejections stated in the communication mailed March 17, 2004, and any ambiguity is regretted.

Objection to the Specification and Claims

The disclosure is objected to because the definition set forth at page 2, lines 3-5, of the specification with which the claimed subject matter must be construed is repugnant to one of ordinary skill in the art. A "phenol oxidizing enzyme" would not be considered by such an artisan to be defined by the result-oriented statement in the specification, viz., "capable of modifying the color associated with dyes and colored compounds having different chemical structures" because this statement admits "compounds having . . . chemical structures" that are "different" than a phenol compound so long as the

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compound is "colored". A further statement at page 5, lines 18-20, of the specification does not improve the non-definition set forth at page 2 therein because it suggests that an enzyme of the claims need only "catalyze redox reactions" and utilize "molecular oxygen and hydrogen peroxide" as oxygen acceptors yet does not indicate that any phenolic compound is a substrate for the enzyme. Claims 2, 3, 39, 42, and 43 are objected to because they recite subject matter defined in the specification in a manner repugnant to common practice in the art.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 39, 42 and 43 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

This is a new ground of rejection. Claims 39 and 42, and claims 2 and 43 depending from claim 39, describe a product of Nature where no claim requires that a "phenol oxidizing enzyme" be purified or isolated from Nature, thus need not describe a product made by a person as required by the statute. Amending claims 39 and 42 to describe, e.g., an "isolated . . . enzyme", as does claim 3, will overcome this rejection.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

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Claim 3 is rejected under 35 U.S.C. § 101 for reasons of record as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,168,936 because, the subject matter described by claim 3 herein is indistinguishable from that of the patented claim. This rejection is a **statutory** double patenting rejection, thus a proper response to this communication requires that claim 3 herein be either amended or canceled.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 39, 42 and 43 are rejected under the judicially created doctrine of double patenting for reasons of record over claims 1, 2, 41 and 42 of U.S. Patent No. 6,168,936 since these claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The recitations of the patented claims 1, 2, 41 and 42 of the issued patent embrace the oxidases of claims 2, 39, 42 and 43 herein because "enzymatic compositions" of patented claims 41 and 42 that comprise a "phenol oxidizing enzyme" of the patented claims 1 and 2 are indistinguishable from the non-isolated, divergent, "phenol oxidizing enzymes" of claims 2, 39, 42 and 43 herein. As no allowable subject matter is present in the claims 2, 39, 42 and 43 pending herein, the rejection of record must be maintained.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the applications that matured into the cited patents. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 2, 39, 42 and 43 are provisionally rejected under the judicially created doctrine of double patenting for reasons of record over claims 9, 11, 61, and 65 of copending Application No. 09/273,957. This is a provisional double patenting rejection

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since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 2, 39, 42 and 43 herein embrace a "phenol oxidizing enzyme" having an amino acid sequence identical to the *S. chartarum* oxidase described by claims 9, 11, 61, and 65 of the copending application. As no allowable subject matter is present in the claims 2, 39, 42 and 43 pending herein, the rejection of record must be maintained.

Claims 2, 39, 42 and 43 are provisionally rejected under the judicially created doctrine of double patenting for reasons of record over claims 1-3 of copending Application No. 10/080,210. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 2, 39, 42 and 43 herein embrace a "phenol oxidizing enzyme" having an amino acid sequence encoded by a nucleic acid sequence capable of hybridizing to SEQ ID NO:1 of the copending application, meeting limitations of claim 1 of the copending application, and describe a "phenol oxidizing enzyme" meeting limitations of claims 2 and 3 of the copending application, wherein the recombinant production of oxidase enzymes in bacterial and yeast host cells is disclosed in the copending application, thus reaches oxidases "obtained from" such sources upon recombinant expression. As no allowable subject matter is present in the claims 2, 39, 42 and 43 pending herein, the rejection of record must be maintained.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 39, 42 and 43 are rejected under 35 U.S.C. § 112, first paragraph, for reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed January 15, 2004, have been fully considered but they are not persuasive. Applicant presents no particular argument traversing the rejection of record and the specification fails to exemplify or describe neither the preparation of a divergent "phenol oxidizing enzyme" of claims 2, 39 and 43, describing generic proteins that may differ at as many as 10% of the amino acid positions of SEQ ID NO:2, i.e., at 59 positions in all, nor the preparation of a divergent "phenol oxidizing enzyme" of claim 42, describing generic proteins that differ at as many as 5% of the amino acid positions of SEQ ID NO:2, i.e., at 30 positions overall. Nor does the specification exemplify or describe the preparation of any "phenol oxidizing enzyme" from any source recited in claim 2 except *S. chartarum*. Neither the claims nor the specification describe where any amino acid sequence differences might occur, nor what such differences might be, and the specification does not otherwise disclose or suggest the nature or source of any generic "phenol oxidizing enzyme" that meets structural limitations of the claims. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification provides no relevant identifying characteristics of "phenol oxidizing enzymes" that diverge at as many as 59, or even 30, amino acid positions within the sequence of SEQ ID NO:2, nor does it provide any characteristic permitting correlation between the undisclosed structures of any of the myriad, generic, "phenol oxidizing enzymes" of claims 2, 39, 42

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and 43 and the amino acid sequence of SEQ ID NO:2. Therefore the rejection of record is maintained.

Claims 2, 3, 39, 42 and 43 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This is a new ground of rejection. Each of claims 2, 3, 39, 42 and 43 recites "phenol oxidizing enzyme" thus each claim is construed according to the definitions discussed above at pages 2 and 5 of the specification: an enzyme requiring no specific substrate for oxidation of "different chemical structures" using "molecular oxygen and hydrogen peroxide" as oxygen acceptors. Yet the specification neither exemplifies nor describes the preparation of an enzyme capable of oxidizing substrates having "different chemical structures" that are not phenolic compounds. Neither the claims nor the specification describe what structures a disclosed enzyme may act on other than phenolic compounds and the specification does not otherwise disclose or suggest the nature of any generic compound having a "chemical structure[]" that is "different" from a phenolic compound. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). There is no particularity in the specification's definitions of a "phenol oxidizing enzyme". Only the assays of the specification's Example 4 provide a particular description of an oxidase, which has the amino acid sequence set forth in SEQ ID NO:2 recognizes the substrate 2,2'-azino-bis-(3-ethyl benzothiazoline-6-sulfonate) [ABTS], thus amending claims 2, 3, 39, 42 and 43 to recite oxidase activity measured with this substrate may overcome this rejection.

Claims 2, 39, 42 and 43 are rejected under 35 U.S.C. § 112, first paragraph, for reasons of record because the specification does not enable preparation of oxidases having amino acid sequences that diverge from the amino acid sequence of SEQ ID NO:2 by amino acid substitutions, deletions and insertions, or combinations thereof, at

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as many as 10%, or even 5%, of the amino acid positions of any of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Applicant's arguments filed January 15, 2004, have been fully considered but they are not persuasive. Applicant presents no particular argument traversing the rejection of record of claims 2, 39, 42 and 43 which claims contemplate arbitrary assignments of any or all of amino acid substitutions, additions or deletions in the disclosed oxidase having the amino acid sequence set forth in SEQ ID NO:2 at as many as 59, or even 30, positions in its primary structure. This rejection is stated under the first paragraph of the statute because the specification does not support nonspecific introductions of 59, or 30, amino acid insertions, deletions, or substitutions anywhere, in any combination or pattern, in the oxidase amino acid sequence set forth in SEQ ID NO:2 that permit retention of its catalytic activity. Indeed, neither the prior art made of record herewith nor Applicant's specification can identify, taken together, thirty amino acids that might be altered, nor teach the nature of any alteration that may be made, that might permit the resulting polypeptide to function as an oxidase as measured by activity with the only substrate disclosed in the specification, ABTS. It is well settled that 35 U.S.C. §112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (recognizing and applying the "Forman" factors). Cf., *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (citing eight factors relevant to analysis of enablement). Applying the "Forman" factors discussed in *Wands*, *supra*, to Applicant's disclosure, it is apparent that:

- a) the specification lacks adequate, specific, guidance for altering the amino acid sequences of the oxidase of SEQ ID NO:2 to the extent permitted in any of claims 2, 39, 42 and 43,

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- b) the specification lacks working examples wherein the oxidase of SEQ ID NO:2, is altered to the extent permitted in any of claims 2, 39, 42 and 43,
- c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,
- d) unpredictability exists in the art where no members of the class of oxidases represented by the amino acid sequence of SEQ ID NO:2, have had as many as thirty amino acids specifically identified for concurrent modification.

The scope of subject matters embraced by the phrases, "having at least 90% [or 95%] identity to", is unsupported by the present specification even if taken in combination with teachings available in the prior art, therefore the rejection of record is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 39, 42 and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 2, 3, 39, 42 and 43 recites the term "phenol oxidizing enzyme" but the artisan and the public seeking to determine the scope of these claims cannot know what is intended by the definitions supporting this term at, e.g., pages 2 and 5 of the specification, where an oxidase of the claims (1) need not recognize any specific substrate for oxidation because a "different chemical structure" other than a phenolic compound is permitted as a substrate according to the specification's definitions and (2) the specification does not disclose that the oxidase having the amino acid sequence set forth in SEQ ID NO:2 recognizes any phenol compound as a substrate.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM

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EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
May 14, 2004



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